



DOCKET NO: C01037.7003.US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Robert L. Bratzler et al.  
Serial No.: 09/776,479  
Confirmation No.: 7139  
Filed: February 2, 2001  
For: IMMUNOSTIMULATORY NUCLEIC ACIDS FOR THE  
TREATMENT OF ASTHMA AND ALLERGY  
Examiner: Q. Nguyen  
Art Unit: 1636

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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, Washington, D.C. 20231, on the 15 day of July, 2003.

Colleen Sullivan  
Colleen Sullivan

Commissioner for Patents  
Washington, D.C. 20231

SUPPLEMENTAL STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing of a first Office Action on the merits.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /NMM/

The Applicant hereby makes the following additional information of record in the above-identified application.

The following co-pending applications that may contain subject matter related to this application are enclosed unless the earlier application is identified herein and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application:

Docket Number	Serial Number	Filing Date	Inventor(s)
C01037.70016.US	09/009,634	1/20/98	Hutcherson et al.
C01037.70021.US	09/949,194	9/7/01	Peterson et al.
C01037.70025.US	10/017,995	12/14/01	Bratzler
C01039.70053.US	09/931,583	8/16/01	Krieg et al.
C01039.70057.US	09/965,101	9/26/01	Davis et al.
C01039.70058.US	10/023,909	12/18/01	Davis et al.
C01039.70060.US	10/112,653	3/29/02	Krieg et al.
C01039.70061.US	10/161,229	6/3/02	Krieg et al.
C01039.70062.US	10/187,489	7/2/02	Krieg et al.
C01039.70063.US	10/224,523	8/19/02	Krieg et al.
C01039.70065.US	10/272,502	10/15/02	Krieg et al.
C01039.70067.US	10/300,247	11/20/02	Davis et al.
C01039.70068.US	10/306,522	11/27/02	Krieg et al.
C01039.70069.US	10/314,578	12/9/02	Krieg et al.
C01039.70070.US	10/382,822	3/6/03	Krieg et al.
C01040.70006.US	09/316,199	5/21/99	McCluskie et al.
C01040.70010.US	09/768,012	1/22/01	Davis et al.
C01041.70016.US	09/954,987	9/17/01	Bauer et al.
C01041.70019.US	10/140,013	5/6/02	Schetter et al.
C01041.70029.US	10/212,133	8/1/02	Lipford et al.
C01041.70031.US	10/265,072	10/5/02	Lipford
C01041.70035.US	10/373,381	2/24/03	Wagner et al.
C01041.70037.US	10/407,952	4/4/03	Wagner et al.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
*Robert L. Bratzler et al., Applicants*



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Maria A. Trevisan, Reg. No.: 48,207  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 720-3500

Docket No. C01037.70013.US  
Date: July 15, 2003  
**XNDDX**

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
JUL 17 2003

FILING DATE: February 2, 2001

CONFIRMATION NO.: 7139

APPLICANT: Robert L. Bratzler et al.

GROUP ART UNIT: 1636

EXAMINER: Q. Nguyen

Sheet 1 of 2

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## U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A20	5,922,766		Acosta et al.	07-13-1999
	A21	6,174,872	B1	Carson et al.	01-16-2001
	A22	6,339,068	B1	Davis, et al.	01-15-2002
	A23	6,406,705	B1	Davis, et al.	06-18-2002
	A24	6,429,199	B1	Krieg et al.	08-06-2002

## FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B36	WO	99/11275	A2	The Regents of the University of California	03-11-1999	
	B37	WO	99/52549	A1	SmithKline Beecham Biologicals S.A.	10-21-1999	
	B38	WO	00/20039	A1	The Regents of the University of California	04-13-2000	
	B39	WO	00/62787	A1	The Regents of the University of California	10-26-2000	

## OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No.	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C165	ARKWRIGHT, P. et al., "Intradermal administration of a killed <i>Mycobacterium vaccae</i> suspension (SRL 172) is associated with improvement in atopic dermatitis in children with moderate-to-severe disease", <i>J. Allergy Clin. Immunol.</i> , March, 2001, pp. 531-534	
	C166	HARTMANN, G. et al., "CpG DNA: A potent signal for growth, activation, and maturation of human dendritic cells", <i>Proc. Natl. Acad. Sci.</i> , August, 1999, vol. 96, pp. 9305-9310	
	C167	HARTMANN, G. et al., "CpG DNA and LPS induce distinct patterns of activation in human monocytes", <i>Gene Therapy</i> , 1999, vol. 6, pp. 893-903	
	C168	IHO, S. et al., "Oligodeoxynucleotides containing palindromic sequences with internal 5'-CpG-3' act directly on human NK and activated T cells to induce IFN- $\gamma$ production <i>in vitro</i> ", <i>J Immunol.</i> , October 1, 1999, vol. 163, no. 7, pp. 3642-3652	
	C169	JAKOB, T. et al., "Bacterial DNA and CpG-containing oligodeoxynucleotides activate cutaneous dendritic cells and induce IL-12 production: implications for the augmentation of Th 1 Responses", <i>Int. Arch. Allergy Immunol.</i> , 1999, vol. 118, pp. 457-461	
	C170	JAKOB, T. et al., "Activation of cutaneous dendrite cells by CpG-containing oligodeoxynucleotides: a role for dendritic cells in the augmentation of Th1 responses by immunostimulatory DNA", <i>J Immunol.</i> , 1998, vol. 161, no. 6, pp. 3042-3049	
	C171	KLINMAN, D. et al., "Contribution of CpG motifs to the immunogenicity of DNA vaccines", <i>J Immunol.</i> , 1997, vol. 158, no. 8, pp. 3635-3639	
	C172	KLINMAN, D. et al., "Immune recognition of foreign DNA: a cure for bioterrorism?", <i>Immunity</i> , August, 1999, vol. 11, pp. 123-129	
	C173	KRANZER K. et al., "CpG-oligodeoxynucleotides enhance T-cell receptor-triggered interferon- $\gamma$ production and up-regulation of CD69 via induction of antigen-presenting cell-derived interferon type I and interleukin-12", <i>Immunology</i> , 2000, vol. 99, pp. 170-178	
	C174	KRIEG, A. et al., "Mechanisms and therapeutic applications of immune stimulatory CpG DNA", <i>Pharmacology &amp; Therapeutics</i> , 1999, vol. 84, pp. 113-120	

/N. M. Minnifield/ (05/06/2009)

Serial No.: 09/776,479 JUL 17 2003  
Conf. No.: 7139

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Art Unit: 1636

EXAMINER

DATE CONSIDERED

/N. M. Minnfield/ (05/06/2009)

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.  
Include copy of this form with next communication to applicant.

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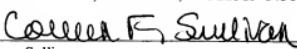
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/N. M. Minnifield/ (05/06/2003)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 15 day of July, 2003.

  
Colleen Sullivan

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Transmitted herewith are the following documents:

- Information Disclosure Statement and USPTO Form 1449  
 Related Applications and Cited References  
 Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

No fee is considered due. If a fee is considered due, the fee may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
Robert L. Bratzler et al., *Applicants*



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Date: July 15, 2003

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